

## **REMARKS**

### **Election/Restriction**

Claims 6-8, 12 and 26-55 have been withdrawn from consideration. Method claims 45-55 have been cancelled without prejudice for possible submission in a continuing application. Withdrawn claims 6-8, 12 and 26-44 have been retained in the pending application for possible reinstatement following allowance of a generic base claim.

### **Claim Rejections – 35 USC §102**

Claims 1-5, 9-11 and 13-25 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,591,170 to Spievack et al. (the “170 reference”). It is well established that “an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989). As set forth below, the Applicant submits that each of the pending independent claims recite elements and/or features that are not disclosed nor suggested in the ‘170 reference or any of the references of record, whether considered alone or in combination.

### **Claims 1-5 and 9**

Independent claim 1 has been cancelled without prejudice for possible submission in a continuing application, dependent claim 9 has been rewritten in independent form, and claims 2, 3 and 6 have been amended to depend from rewritten independent base claim 1.

Rewritten independent claim 9 recites, in pertinent part, a surgical instrument comprising an elongate member and at least one cutting element that is transitionable between a retracted configuration and an expanded configuration, and wherein a portion of the elongate member

defines “a tapping thread configured to cut threads along the first portion of the passage”, and wherein the expanded configuration of the at least one cutting element forms an enlarged cross-sectional portion of the passage. The Applicant respectfully traverses the rejection of claim 9 for at least the following reasons.

Contrary to the assertions set forth in the Office Action, the reamer tip 610 disclosed in the ‘170 reference (FIG. 10; col. 6, ll. 35-49) is not “configured to cut threads along the first portion of the passage”. Indeed, there is no teaching or suggestion in the ‘170 reference that the reamer tip 610 is configured to cut or form threads in bone. Instead, the reamer tip 610 is used “for boring the intramedullary canal” of a bone. (See, e.g., Abstract, ll. 9-10; claim 23). The term “reamer” has a well-accepted meaning to those of skill in the art to which the present invention relates. Specifically, a reamer typically refers to a tool that is used to enlarge or smooth out an opening in bone or other tissue. However, a reamer does not include tapping threads or any other element or feature that could be used to cut threads in bone. Further, the dictionary definition of “reamer” is “a steel tool with a cylindrical or tapered shank around which longitudinal teeth are ground, used for smoothing the bores of holes accurately to size.” (The Collins English Dictionary © 2000, HarperCollins Publishers). As should be appreciated, smoothing or enlarging a bore actually teaches away from the concept of forming threads along such a bore.

Additionally, the reamer tip 610 appears to have a tapered configuration including a number of concentric, axially-offset cutting elements, with the concentric cutting elements clearly perform a boring function as opposed to a tapping function. As further evidence that the reamer tip 610 is not configured to form threads along a passage, there is no indication or

suggestion whatsoever in the '170 reference that a threaded member (e.g., a screw) is subsequently threadingly inserted into the passage formed in the intramedullary canal by the bone saw.

There is no indication whatsoever that the reamer tip 610, or any portion of the bone cutting saw for that matter, cuts threads along the interior of the intramedullary canal. Additionally, neither the bone cutting instrument of the '170 reference nor any of the instruments or devices disclosed in the references of record teach the use of an instrument that is configured to cut threads along a passage in bone and to form an enlarged cross-sectional portion of the passage. This unique combination of features is neither disclosed nor suggested by the '170 reference or any of the references of record.

For at least the reasons discussed above, rewritten independent claim 9 is patentable over the '170 reference and the other references of record, whether considered alone or in combination. Additionally, dependent claims 2-5 are patentable for at least the reasons supporting the patentability of independent base claim 9.

**Claims 10, 11 and 13-19**

Independent claim 10 has been cancelled without prejudice for possible submission in a continuing application, dependent claim 11 has been rewritten in independent form, and claims 12, 13 and 15 have been amended to depend from rewritten independent base claim 11. Additionally, independent claims 14 and 18 have also been rewritten in independent form.

Rewritten independent claims 11 and 18 each recite, in pertinent part, a surgical instrument comprising a first cutting element comprising "a tapping thread" for forming a threaded portion of a passage in bone, and a second cutting element transitionable to an

expanded configuration for forming an enlarged cross-sectional portion of the passage. As discussed above, the reamer tip 610 disclosed in the '170 reference does not include a "tapping thread" nor any element or feature structurally or functionally similar to a tapping thread. Additionally, rewritten independent claim 14 recites, in pertinent part, a surgical instrument comprising a first cutting element for forming a first portion of a passage which is "configured to be self-drilling and self-tapping", and a second cutting element transitionable to an expanded configuration for forming an enlarged cross-sectional portion of the passage. Once again, the reamer tip 610 disclosed in the '170 reference is not configured to be "self tapping". Indeed, there is no indication or suggestion of tapping the intramedullary canal, much less tapping the intramedullary canal via the use of the reamer tip 610. Additionally, the reamer tip 610 does not appear to be "self-drilling", but is instead used to enlarge or smooth out a pre-existing opening in bone (i.e., the intramedullary canal).

For at least the reasons discussed above, rewritten independent claims 11, 14 and 18 are patentable over the '170 reference and the other references of record, whether considered alone or in combination. Additionally, dependent claims 12, 13 and 15-17 are patentable for at least the reasons supporting the patentability of independent base claim 11, and dependent claim 19 is patentable for at least the reasons supporting the patentability of independent base claim 18.

#### **Claims 20-23**

Independent claim 20 recites, in pertinent part, "a tapping thread . . . for forming a threaded portion of a passage in bone" and a cutting blade transitionable between a retracted configuration for extending through the threaded portion of the passage and an expanded configuration for forming an enlarged cross-sectional portion of the passage. As discussed

above, the reamer tip 610 disclosed in the '170 reference does not include a "tapping thread" nor any other element or feature that could be used for forming a threaded portion of a passage in bone. For at least these reasons, independent claim 20 is patentable over the '170 reference and the other references of record, whether considered alone or in combination. Additionally, dependent claims 21-23 are patentable for at least the reasons supporting the patentability of independent base claim 20.

#### **Claim 24**

Independent claim 24 recites, in pertinent part, "means for tapping threads along a portion of a passage in bone" and "means for forming an enlarged cross-sectional portion of the passage". As discussed above, the reamer tip 610 disclosed in the '170 reference does not include any element or function for use in "tapping threads along a portion of a passage in bone". For at least these reasons, independent claim 24 is patentable over the '170 reference and the other references of record, whether considered alone or in combination.

#### **Claim 25**

Independent claim 25 has been amended to recite, in pertinent part, an elongate member including "a tapping portion . . . configured to cut threads along a passage in bone" and an expandable portion having at least one cutting element transitionable between an axial orientation and an angular orientation for enlarging a portion of the axial passage laterally adjacent the threads. Once again, the reamer tip 610 disclosed in the '170 reference does not include any element or function that is configured to cut threads along a passage in bone, nor does the bone saw disclosed in the '170 reference disclose a cutting element having an angular orientation for enlarging a portion of the axial passage laterally adjacent the threads. For at least

these reasons, amended independent claim 25 is patentable over the '170 reference and the other references of record, whether considered alone or in combination.

**Claims 56-61**

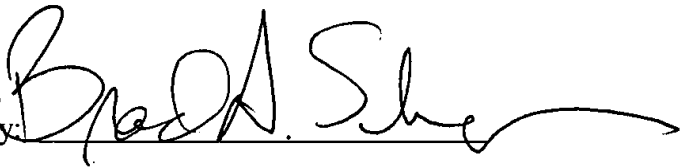
New claims 56-61 have been added to the present application. New independent claim 56 recites, in pertinent part, "a tapping element" formed along a distal portion of an elongate member and "configured to cut threads" along a passage in bone, and at least one cutting element transitionable between a retracted configuration and an expanded configuration for enlarging a portion of the passage laterally adjacent the threads. These elements and features are neither disclosed nor suggested in the '170 reference or any of the references of record, whether considered alone or in combination. Additionally, dependent claims 57-61 are patentable for at least the reasons supporting the patentability of independent base claim 56.

## CONCLUSION

In view of the foregoing remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 2-9, 11-44 and 56-61.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

By: 

Brad A. Schepers  
Reg. No. 45,431  
Woodard, Emhardt, Moriarty,  
McNett & Henry LLP  
Bank One Center/Tower  
111 Monument Circle, Suite 3700  
Indianapolis, Indiana 46204-5137  
(317) 634-3456 voice  
(317) 637-7561 facsimile